DETAILED ACTION

Restriction Requirement

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-20, drawn to a method of treating a patient comprising administering a Cathepsin S inhibitor.

Group II, claim(s) 21-25, drawn to a method of making a medicament comprising a Cathepsin S inhibitor. (see **Examiner's Note**)

Examiner's Note:
Claims 21-25 recite non-statutory "use" claims. See MPEP 2173.05(q). Examiner has interpreted claims 21-25 as being drawn to a method of making a medicament.

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The common feature of the inventions of Groups I and II is a Cathepsin S inhibitor. However, a Cathepsin S inhibitor is a known product. See Saegusa et al. (The Journal of Clinical investigation, 2002, 110, p361-369, provided by Applicant on IDS filed 16 Oct 2006), page 361, right column, lines 29-31. Therefore a Cathepsin S inhibitor is not the special technical of a single general inventive concept. The special technical feature of the invention of Group I is the specific steps of the method of treating a patient using a specific Cathepsin S inhibitor. The special technical feature of the invention of Group II is the specific steps of method of making a medicament comprising a specific Cathepsin S inhibitor.

Species Election Requirement

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

If Applicant restricts to the invention of Group I, Applicant is required to elect from both the following **first** and **second** species elections.

If Applicant restricts to the invention of Group II, Applicant is required to elect from the following **first** species election.

First Species Election:

This application contains claims directed to more than one species of Cathepsin S inhibitor of the generic invention. These species are deemed to lack unity of invention/n because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. The species of Cathepsin S inhibitor exhibit a specific chemical structure.

The species of Cathepsin S inhibitor are as follows, disclosed in claim 20:

7-(2,2-dimethylpropyl)-6-thiophen-2-ylmethyl-7H-pyrrolo-[2,3-d]pyrimidine-2-carbonitrile;

morpholine-4-carboxylic acid [(S)-1-(4-cyano-1-methylpiperidine-4-ylcarbamoyl)-4,4-dimethylhexyl]amide;

morpholine-4-carboxylic acid [(S)-1-(4-cyano-1-propylpiperidine-4-ylcarbamoyl)-3,3,4,4-tetramethylpentyl]amide;

morpholine-4-carboxylic acid [(S)-1-(4-cyano-1-propylpiperidine-4-ylcarbamoyl)-4,4-dimethylpentyl]amide;

morpholine-4-carboxylic acid [(S)-1-(4-cyano-1-propylpiperidine-4-ylcarbamoyl)-4,4-dimethylhexyl]amide;

morpholine-4-carboxylic acid [(R)-1-(4-cyano-1-methylpiperidine-4-ylcarbamoyl)-4,4-dimethylhexyl]amide;

5,5-dimethyl-2-(2-oxo-2H-benzo[e][1,3]oxazin-4-ylamino)heptanoic acid (4-cyano-1-propylpiperidin-4-yl)amide;

5,5-dimethyl-2-(2-oxo-2H-benzo[e][1,3]oxazin-4-ylamino)heptanoic acid (4-cyano-1-(3-morpholin-4-ylpropyl)piperidin-4-yl)amide;

5,5-dimethyl-2-(2-oxo-2H-benzo[e][1,3]oxazin-4-ylamino)heptanoic acid (4-cyano-1-(2-morpholin-4-ylethyl)piperidin-4-yl)amide;

5,5-dimethyl-2-(2-oxo-2H-benzo[e][1,3]oxazin-4-ylamino)heptanoic acid {4-cyano-1-[2-(2-methoxyethoxy)ethyl]piperidin-4-yl}amide;

5,5-dimethyl-2-(2-oxo-2H-benzo[e][1,3]oxazin-4-ylamino)heptanoic acid (4-cyano-1-methylpiperidin-4-yl)amide;

2-(7-fluoro-2-oxo-2H-benzo[e][1,3]oxazin-4-ylamino)-5,5-dimethylheptanoic acid (4-cyano-1-propylpiperidin-4-yl)amide;

2-(7-fluoro-2-oxo-2H-benzo[e][1,3]oxazin-4-ylamino)-5,5-dimethylhexanoic acid {4-cyano-1-(2-morpholin-4-ylethyl)piperidin-4-yl}amide;

2-(7-fluoro-2-oxo-2H-benzo[e][1,3]oxazin-4-ylamino)-5,5-dimethylhexanoic acid {4-cyano-1-[2-(2-methoxyethoxy)ethyl]piperidin-4-yl}amide; or

One compound according to one of formula (Ia), formula (Ib), formula (II), or formula (III), and wherein the species of each functional group in the elected formula, for example represented by R^1, E, Q, Z or X^1, is elected (for example 2S-acetylamino-N-(2-oxazol-2-yl-2-hydroxy-1S-phenethyl)-3-cyclohexylpropionamide disclosed in the specification on page 13, line 5).

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election. Applicant is cautioned that election of a genus of compounds, such as “a compound according to formula (Ia)”, or a genus of compounds containing a genus of functional groups, such as a compound according to formula (Ia) wherein R^1, R^{1a}, R^2, R^3, and R^4 are alkyl”, will be considered non-responsive. Species of a genus such as “alkyl” may be found in the specification, for example “methyl” or “ethyl” disclosed on page 56, line 2.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:
All claims are generic to the Cathepsin S inhibitor.

If Applicant restricts to the invention of Group I, Applicant is required to elect from both the **first** and **second** species elections.

Second Species Election:

This application contains claims directed to more than one species of method of treating a patient undergoing non-tissue graft therapy of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. The species of method of treating a patient undergoing non-tissue graft therapy involves therapy with a species of agent.

The species of agent involved in the therapy of the species of method of treating a patient undergoing non-tissue graft therapy are as follows, disclosed in claims 4 and 8:

heparin,

low molecular weight heparin,

procainamide,

hydralazine,

Remicade®,

Refacto®,

Referon-A®,

Factor VIII,

Factor VII,

Betaseron®,

Epogen®,

Embrel®,

Interferon beta,

Botox®,

Fabrazyme®,

Elspar®,

Cerezyme®,

Myobloc®,

Aldurazyme®,

Verluma®,

Interferon alpha,

Humira®,

Aranesp®,

Zevalin®,

OKT3, or

non-tissue graft therapy with a small molecule therapeutic that is specifically not any of the above agents, or

non-tissue graft therapy with a biologic that is specifically not any of the above agents.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election. Applicant is cautioned that election of a genus, such as "antibody", "protein" or "small molecule therapeutic", will be considered non-responsive.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

All claims are generic to the species of method of treating a patient undergoing non-tissue graft therapy.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The common feature of the inventions of Groups I and II is a Cathepsin S inhibitor. However, a Cathepsin S

inhibitor is a known product. See Saegusa et al. (The Journal of Clinical investigation, 2002, 110, p361-369, provided by Applicant on IDS filed 16 Oct 2006), page 361, right column, lines 29-31. Therefore a Cathepsin S inhibitor is not the special technical of a single general inventive concept. The special technical feature of the invention of Group I is the specific steps of the method of treating a patient using a specific Cathepsin S inhibitor. The special technical feature of the invention of Group II is the specific steps of method of making a medicament comprising a specific Cathepsin S inhibitor.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan S. Lau whose telephone number is 571-270-3531. The examiner can normally be reached on Monday - Thursday, 9 am - 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisors, Ardin Marschel can be reached on 571-272-0718 or Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JSL

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